

REMARKS

Upon entry of the foregoing amendment, claims 17, 18, 20, and 22, and new claims 24-37, are pending in the application, with claims 19, 21, and 23 canceled without disclaimer of, or prejudice to, the material claimed therein. Claims 1-16 are withdrawn by the Examiner under 37 C.F.R. § 1.142(b). Claims 17, 18, 20 and 21 stand rejected under 35 U.S.C. § 103(a).

Claim 17 is amended to clarify that the means for inducing a current in the first solenoid acts such that the first solenoid coil emits an electromagnetic field having a magnetic flux density from about 5×10^{-6} gauss to about 1×10^{-12} gauss and a frequency between 0 and 140 Hertz, as described in the specification at ¶ 13 (page 4) of the specification. Claim 22 is amended to correct the syntax of the claim. Also, new claims 24-37 are added to more specifically describe magnetic resonance windows for the device. Support for new claims 24-37 is found in the specification at ¶ 34 (pages 8-9) and Table 3 which describes the frequency ranges associated with each of the claimed magnetic field ranges.

The specification, including Table 3, is amended to correct typographical errors. Also, Table 3 is amended to fill in values based on the formulas and values given for velocity (v), length (L), and field (B) immediately preceding the Table on page 12 of the specification.

Accordingly, no new matter is added by the amendment of the specification or claims.

Interview Summary

A telephone interview was held on July 24, 2006. Present at the interview were the Examiner, Michael Kahelin, the Applicant, Jerry Jacobson, Applicant's representative, Cynthia Rothschild, and Mr. Allen Braswell. Discussed was the rejection of the claims as unpatentable under 35 U.S.C. § 103(a) over Patent No. 6,004,257 to Jacobson (Jacobson-1), in view of U.S. Patent Application Publication 2005/0060011 to Denker ("Denker") and U.S. Patent Application Publication US 2002/0026228 to Schauerte ("Schauerte"). The Applicant and Applicant's representative presented arguments that one would not be motivated to combine the cited references, and that the

combined references did not describe, teach or suggest all of the limitations of the claims, in that Jacobson-1 was directed to the treatment of a subject with externally applied magnetic fields, and that Denker and Schauerte each addressed the application of very different types of internal devices than Applicant's claimed device. The Examiner indicated that the Applicant's arguments were persuasive and suggested that Applicant present such arguments in the filed response.

The Applicant and Applicant's representatives thank the Examiner for conducting the interview and helping to resolve the outstanding issues in the case.

The Rejection of Claims Under 35 U.S.C. § 103(a) is Traversed Or Rendered Moot

Claim 22

The Examiner rejected claim 22 as being unpatentable under 35 U.S.C. § 103(a) over U.S. Patent No. 6,004,257 to Jacobson ("Jacobson-1") in view of U.S. Patent Application Publication 2005/0060011 to Denker ("Denker"). Thus, the Examiner stated that:

Jacobson discloses the essential features of the claimed invention including the following: a device for stimulating organ operation (specifically improving the functional ability of the heart (col. 7, line 24) comprising a means for inducing an electric current in a solenoid coil for emitting EMFs with the claimed magnetic flux density and frequency (abstract) external to the organism (Fig. 3). Furthermore, the generator comprises a second (external) solenoid (6), an attenuator (1, i.e., the water contained in the tank), and a signal generator (3) . . . [T]he generator of Jacobson is capable of inducing an electric current in a solenoid coil for emitting EMFs with the claimed magnetic flux density and frequency because the magnetic flux permeates the subject's entire body (Fig. 3). Jacobson does not disclose a first solenoid operatively coupled to a capacitor. Denker teaches of providing a first solenoid operatively coupled to a capacitor (par. 0027) in the form of a stent (Fig. 2) to remotely provide pacing therapy to a heart and serve as an antenna for a device external to the first solenoid.

Office Action at pages 2-3.

The Federal Circuit has stated that "[i]n order to render a claimed apparatus or method obvious, the prior art must enable one skilled in the art to make and use the apparatus or method." *Motorola, Inc. v. Interdigital Technology Corp.*, 43 U.S.P.Q. 2d

1481, 1489 (Fed. Cir. 1997) (quoting *Beckman Instruments, Inc. v. LKB Produkter AB*, 13 U.S.P.Q. 2d 1301, 1304 (Fed. Cir. 1989)). Also, subsection 706.02(j) of the MPEP states that to establish a *prima facie* case of obviousness three criteria must be met:

- (i) a suggestion or motivation to modify or combine references;
- (ii) a reasonable expectation of success; and
- (iii) all the limitations in the claim(s) must be taught or suggested by the reference, or combination of references.

The Applicant respectfully asserts that the references do not establish a *prima facie* case of obviousness. Thus, Applicant respectfully asserts that there would not be a motivation or suggestion to modify or combine the references to arrive at Applicant's invention. Nor would not be a reasonable expectation of success that the references could be modified to arrive at Applicant's claimed invention. Finally, Applicant respectfully asserts that Jacobson-1 and Denker do not teach or suggest all of the limitations of Applicant's claimed invention.

No Motivation to Combine

Applicant respectfully asserts that one would not be motivated to combine Jacobson-1 with Denker to arrive at Applicant's invention because Denker is directed to a very different problem, and describes a very different technology, than Jacobson-1.

Jacobson-1 describes a device that is completely external to the subject being treated. The device of Jacobson-1 is designed to expose an entire subject to alternating and steady magnetic fields ranging from a flux density of about 10^{-6} gauss to 10^{-20} gauss and a frequency from about 0 Hz to 140 Hz as a means to target specific biomolecules (e.g., DNA) and biological structures (e.g., neuronal cells) to rejuvenate such biomolecules and structures so as to reduce the effects of aging. There is no teaching in Jacobson-1 that the technology may be adapted to be used as a device implanted within the subject's body. Thus, nowhere in Jacobson-1 is it described, taught, or suggested that the application of a low level magnetic field could be accomplished using an internal device.

In contrast, Denker is concerned with using a transmitting antenna for remote control of a pacemaker. Denker is concerned with designing an omnidirectional antenna such that a signal to a pacemaker will be received regardless of the patient's orientation.

The remotely controlled pacemaker of Denker utilizes signals of a much higher strength than the magnetic fields taught by Jacobson-1, to generate electric pulses that are of an amplitude and frequency so as to directly stimulate a heart beat. Also, the radiofrequency signal of Denker is an intermittent pulse that functions in a very different manner than the low level, magnetic field used to generate Jacobson Resonance as described in Jacobson-1. Denker describes that the radio frequency signal is on the order of 27 MHz, in contrast to the frequency range of 0 to 140 Hz used with Jacobson Resonance.

Because Denker teaches a solution to an entirely different type of apparatus and problem than the apparatus in Jacobson-1, one would not be motivated to combine the radiofrequency driven pacemaker device of Denker which is designed for the application of a burst of voltage for stimulation of the heart, with the external magnetic field, ranging from 10^{-12} gauss to 10^{-6} gauss of Jacobson-1, to thereby arrive at Applicant's invention.

No Expectation of Success

Jacobson-1 describes a device that is completely external to the subject being treated. As described above, the device of Jacobson-1 is designed to expose an entire subject to alternating and steady low-level magnetic fields to target specific biomolecules and biological structures as a means to reduce the effects of aging.

An important premise of Jacobson-1 is that the subject's orientation should be relatively fixed (i.e., generally orthogonal) with respect to the orientation of the applied magnetic field, and that application of the magnetic field should take into account the position of the earth relative to the sun. See Jacobson-1, Figures 1-11, and columns 4-5. Also, in contrast to the internal device of the present invention, Jacobson-1 teaches the use of water as a means to facilitate alignment of the magnetic poles of biomolecules or cells in the subject and cooperativity of oscillator frequencies of water molecules comprising the biosystem.

There is no teaching, description, or suggestion in Jacobson-1 that a low level electromagnetic radiation (i.e., Jacobson Resonance) emitted as a device implanted internal to the organism would act in a similar manner as the use of such electromagnetic radiation externally applied. The interaction of such a low-level electromagnetic field inside of the body was not necessarily anticipated to function in a similar manner as the application of the radiation external to the subject.

Nor is there anything in Denker which, in combination with Jacobson-1, provides a basis for expecting that use of an internally applied magnetic field would be successful. Denker is concerned with using a radio frequency signal to drive a cardiac pacemaker device. The device of Denker is thus concerned with the application of a non-physiological, discrete signal upon the determination that a heart stimulation pulse is required. There is no teaching in Denker relating to the use of internally applied physiologic or therapeutic magnetic fields, or how such fields might be applied. Thus, Applicant respectfully asserts that Denker does not remedy the deficiencies of Jacobson-1 such that the combination of the references provide an expectation that use of an internal stent for the application of a magnetic field ranging from 10^{-12} gauss to 10^{-6} gauss for treatment of an internal organ would be successful.

Not All Limitations Are Taught Or Suggested

As discussed above, Jacobson-1 describes a device that is completely external to the subject being treated. The device of Jacobson-1 is designed to expose an entire subject to alternating and steady magnetic fields ranging from a flux density of about 10^{-6} gauss to 10^{-20} gauss and a frequency from about 0 Hz to 140 Hz to reduce the effects of aging. There is no teaching or suggestion in Jacobson-1 that the technology may be adapted to be used as a device implanted within the subject's body. Thus, nowhere in Jacobson-1 is it described, taught, or suggested that the application of a low level magnetic field could be accomplished using an internal device as described in Applicant's specification. Nor is there any teaching in Jacobson-1 that such an internal device could be used to modify specific aspects of cardiac function, such as heart rate (e.g., Figures 2 and 3) or changes in A-H intervals (e.g., Figure 4), or that narrow windows could be developed to specifically target sympathetic or parasympathetic nerve function (new claims 24-37) which describe ranges for affecting autonomic input of ganglionated plexes located in fat pads on the heart.

Also, there is absolutely no teaching, description, or suggestion in Jacobson-1 as to how to utilize an external solenoid in conjunction with an internal solenoid such that when the external solenoid coil is activated, the electromagnetic radiation is translated to induce a magnetic field having a flux of about 5×10^{-6} gauss to about 1×10^{-12} gauss and a frequency between 0 and 140 Hertz.

Nor does Denker remedy the deficiencies of Jacobson-1. Denker does describe a capacitor coupled to a solenoid. However, the signals received and generated by the pulse maker and signal generator of Denker are much stronger than the low-level magnetic fields utilized in Applicant's invention. Also, the radiofrequency signal of Denker is an intermittent pulse that functions in a very different manner than the low level, magnetic field used in the implanted stent of Applicant's claimed invention.

For at least these reasons, Applicant respectfully asserts that the Examiner has not established a *prima facie* case that claim 22 is obvious over Jacobson-1 in view of Denker and requests that the rejection be withdrawn.

Secondary Considerations

Without in any way acquiescing that the Examiner has established a *prima facie* case of obviousness, Applicant respectfully asserts that secondary considerations further substantiate that Applicant's claimed composition is not obvious in view of the cited references. The application of concomitant internally and externally applied magnetic fields provides an unexpected benefit in that it allows for the magnetic profiles of any nearby structures to be better adjusted and thereby to minimize any interference and/or attenuation of discrete signals. Although in some cases the internal magnetic field alone is sufficient, the use of both internal and external magnetic fields in combination allows for renormalization of the magnetic profiles of multiple structures that may regulate cardiac function, such as any autonomic input signaling to the heart.

Claims 17, 18, and 20

The Examiner rejected claims 17, 18 and 20 as being unpatentable under 35 U.S.C. § 103(a) over Jacobson-1, Denker, and U.S. Patent Application Publication US 2002/0026228 to Schauerte ("Schauerte"). Thus, the Examiner stated:

The invention of Jacobson, as modified above, discloses the essential features of the claimed invention, including an attenuator operatively coupled to the control circuitry (Denker, par. 0027), but does not disclose a second solenoid, with a first wire, second wire, and attenuator, and further comprising a catheter removably insertable into the first solenoid. Schauerte teaches of providing a first solenoid coil (Fig. 11, element 2.11) with a second solenoid (7) having a first wire (unlabelled left straight section of coil), a second wire (unlabelled right straight

section of coil), and a signal generator (10) external to the body (par. 0018) . . . and further comprising a catheter removably inserted into the first solenoid to provide stimulation energy to the first solenoid (Fig. 11).

Office Action at page 3.

The Applicant respectfully asserts that the references do not establish a *prima facie* case of obviousness that claims 17, 18 and 20 are unpatentable under 35 U.S.C. § 103(a). Thus, Applicant respectfully asserts that there would not be a motivation or suggestion to modify or combine the references to arrive at Applicant's invention. Nor would not be a reasonable expectation of success that the references could be modified to arrive at Applicant's claimed invention. Nor do the references teach or suggest all of the limitations of Applicant's claimed invention.

No Motivation to Combine

The Applicant respectfully asserts that for the reasons asserted herein, Jacobson-1 does not teach or suggest a first internal solenoid coil for emitting electromagnetic fields having a magnetic flux density from about 5×10^{-6} gauss to about 1×10^{-12} gauss and a frequency between 0 and 140 Hertz and sized to be implanted in an internal blood vessel or organ as is required by claims 17, 18 and 20. Nor is there any suggestion in Jacobson-1 that a second internal coil may be used to induce a magnetic field in the first coil. Jacobson-1 discloses applying a magnetic field to an organism where the device is completely external to the organism. There is absolutely no description in Jacobson-1 as to how one would adapt a device comprising an external solenoid (or Helmholtz coil) for applying Jacobson Resonance to work as a completely internal device.

Nor would one be motivated to combine Jacobson-1 with Denker and Schauerte to arrive at Applicant's invention. As described above, Denker is directed to a very different problem and describes a very different technology than Jacobson-1. The remotely controlled pacemaker of Denker utilizes qualitatively different electromagnetic signals of a much higher strength, to generate electric pulses that are of an amplitude and frequency to directly stimulate a heart beat. Thus, the signals received and generated by the pulse maker and signal generator of Denker are much stronger than the low-level magnetic fields utilized in Applicant's invention.

Also, the electrode of Schauerte utilizes pulses of 50 to 1,000 volts having a frequency of 10-100 Hz as a means to stimulate nerves (See Schauerte at ¶ 22). Thus, Schauerte uses high voltage impulses that are non-physiologic, and that result in either nerves or muscles (e.g., the heart) responding to the stimulus in a transient and non-physiological manner. In contrast, the apparatus of the claimed invention uses low level magnetic fields to allow the heart to restore it's own intrinsic rhythm by molecular restructuring and renormalization of function which results from application of the magnetic field.

Because Denker and Schauerte each describe very different types of devices than the apparatus in Jacobson-1, one would not be motivated to combine the radiofrequency driven pacemaker device of Denker, or the electrode of Schauerte, with the external device for generating a magnetic field ranging from 10^{-12} gauss to 10^{-6} gauss of Jacobson-1, to thereby arrive at Applicant's invention.

Expectation of Success

For the reasons described above, upon reading Jacobson-1 there was no expectation of success that an internal device could be used to apply low level magnetic fields to the heart and surrounding vasculature.

Nor is there anything in Denker or Schauerte that in combination with Jacobson-1, provides a basis for expecting that use of an internally applied magnetic field would be successful. Denker is concerned with using a radio frequency signal to drive a cardiac pacemaker device. There is no teaching in Denker relating to the use of internally applied therapeutic magnetic fields, or how such fields might be applied. Also, the electrode of Schauerte utilizes pulses of 50 to 1,000 volts having a frequency of 10-100 Hz as a means to stimulate nerves. Thus, Schauerte uses high voltage impulses that are non-physiologic, and that result in either nerves or muscles (e.g., the heart) responding to the stimulus in a transient manner. Thus, Applicant respectfully asserts that neither Denker nor Schauerte remedy the deficiencies of Jacobson-1 such that the combination of the references provide an expectation that use of an internal stent for the application of a magnetic field ranging from 10^{-12} gauss to 10^{-6} gauss for treatment of an internal organ would be successful.

Not All Limitations Are Taught Or Suggested

Finally, Applicant respectfully asserts that, for the reasons stated above, Jacobson-1 does not describe, teach, or suggest that the application of a low level magnetic field could be accomplished using an internal device as described in Applicant's specification. Nor is there any teaching in Jacobson-1 that such an internal device could be used to modify specific aspects of cardiac function, such as heart rate (e.g., Figures 2 and 3) or changes in A-H intervals (e.g., Figure 4), or that narrow windows could be developed to specifically target sympathetic or parasympathetic nerve function (new claims 24-37).

Neither Schauerte or Denker remedy the deficiencies of Jacobson-1. Thus, the signals received and generated by devices of Denker and Schauerte are much stronger than the low-level magnetic fields utilized in Applicant's invention. Also, the signals of Denker and Schauerte are intermittent pulses that function in a very different manner than the low level, magnetic field used in the implanted stent of Applicant's claimed invention. Both Denker and Schauerte are concerted with applying electric pulses to the heart and/or other organs in a manner to influence the electrical function of such organs and do not teach or describe how to apply low-intensity magnetic fields that provide a renormalizing and therapeutic effect.

For at least these reasons, Applicant respectfully asserts that the Examiner has not established a *prima facie* case that claims 17, 18 and 20 are obvious under 35 U.S.C. § 103(a) over Jacobson-1 in view of Denker and Schuarte, and requests that the rejection be withdrawn.

CONCLUSION

In view of the foregoing amendment and remarks, each of the claims remaining in the application is in condition for immediate allowance. The Examiner is respectfully invited to telephone the undersigned at (336) 747-7541 to discuss any questions relating to the application.

Respectfully submitted,

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